BeamMed
Focused On Bone Health

K110646

OCT 1 2 2011

BeamMed Ltd.
8 Ha-Lapid Street
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Israel

# Appendix B

## 510(k) Summary in accordance with 21 CFR 807.92(c)

| | |
|---|---|
| **Device Name:** | BeamMed MiniOmni Bone Sonometer |
| **Type of 510(k) submission:** | Abbreviated |
| **Date of Submission:** | 24 February 2011 |
| **Manufacturer:** | BeamMed Ltd.<br>8 Halapid Street<br>Petach Tikva<br>ISRAEL 49170 |
| **FDA Establishment Registration Number:** | 3006701790 |
| **510(k) Owner:** | BeamMed Ltd.<br>8 Halapid Street<br>Petach Tikva<br>ISRAEL 49170 |
| **Trade Name:** | BeamMed Sunlight MiniOmni Bone Sonometer |
| **Common Name:** | Bone Sonometer |
| **Class:** | Class II |
| **Product Codes:** | MUA |
| **Classification Regulation:** | 892.1180 |
| **Predicate Device:** | Sunlight Omnisense 7000 Bone Sonometer |
| **Predicate Device Manufacturer:** | BeamMed Ltd.<br>8 Halapid Street<br>Petach Tikva<br>ISRAEL 49170 |

**Device Description:**

The Sunlight MiniOmni Ultrasound Bone Sonometer is a noninvasive device that consists of:

(1) Main unit, which contains an ultrasound transmission / reception printed circuit board (ultrasound PCB) and mechanical and electric elements for connecting the ultrasound probes
(2) User interface and algorithmic calculation software provided in installation disc
(3) Hand-held probes (choice from 3 ultrasonic probe types already PMA-approved, plus one new probe)
(4) Medical grade AC to DC power adaptor and cable
(5) USB Connection cable
(6) System quality verification (SQV) phantom;
(7) Spring-loaded positioning gauge;
(8) Cushioned hand rest
(9) User Guide

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(10) Ultrasound gel (optional accessory)
(11) Skin marker pencil (optional accessory)
(12) Foot pedal (optional accessory)
(13) Sterile disinfection towelettes (optional accessory)
(14) Carrying case for easy mobility (optional accessory)

The MiniOmni requires connection to a stand-alone computer and visual display unit provided by the user in order to operate as intended.

The MiniOmni has been developed from the Sunlight Omnisense 7000S device, which was originally approved for sale in the US by means of PMA P990035. In August 2008, FDA down-classified Bone Sonometers in Product Code MUA to Class II, special controls. This 510(k) submission identifies the Omnisense 7000S as the predicate device against which substantial equivalence is demonstrated.

The functionality of the MiniOmni is not significantly different from the Omnisense 7000S, although the Omnisense 7000s included an integral computer and visual display unit. The fundamental technology and operating principles are the same as the Omnisense 7000S. The acoustic components (algorithm, analog card, and probes) of the MiniOmni are identical or functionally equivalent to those of the Omnisense 7000S.

Three ultrasound probes (codes CMB, CRB and CSB), the SQV phantom, spring-loaded positioning gauge, and cushion hand rest are identical to those included in the PMA–approved Omnisense 7000S system. A fourth, new CMC probe has a modified assembly process when compared with the standard CMB probe, in order to provide more stable operation in humid environments.

The MiniOmni has been designed to take advantage of electronic miniaturization and updated hardware components that have become available since design and development of the Omnisense 7000S. These modifications, however, have not changed the fundamental technology or operating principles used in the Omnisense 7000S.

The software of the MiniOmni includes certain minor modifications from the predicate Omnisense 7000S software in order to allow for proper hardware communication as a result of the electronic hardware updates mentioned previously. Additionally, several user convenience features have been added to the software. All of the software differences between the MiniOmni and the Omnisense 7000S were qualified through appropriate testing using standard test methods and approved protocols to demonstrate that each function was working properly in the integrated software.

the MiniOmni software is composed of three main subsystems according to the device's hardware architecture:

(1) The PC subsystem;
(2) The digital PCB Subsystem; and
(3) The PC-digital PCB Interface Subsystem.

**Indications for Use:**

The Sunlight MiniOmni Ultrasound Bone Sonometer is a non-invasive device that is designed for the quantitative measurement of the signal velocity of ultrasound waves ("Speed of Sound" or "SOS" in m/sec) propagating at multiple skeletal sites (i.e., the distal one-third of the radius, the proximal third phalanx and the fifth metatarsal). SOS provides an estimate of skeletal fragility.

The output is also expressed as a T-score and a Z-score, and can be used in conjunction with other clinical risk factors as an aid to the physician in the diagnosis of osteoporosis and other

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medical conditions leading to reduced bone strength and, ultimately, in the determination of fracture risk.

Multiple skeletal site testing provided clinicians with alternatives if one site is not accessible and with additional skeletal information (i.e., from bones with different combinations of cortical and cancellous material and from weight bearing and non-weight bearing sites) that assists in diagnosing osteoporosis and risk fracture.

The SOS measured by MiniOmni has a precision error low enough in comparison with the expected annual change in a patient's measurement to make it suitable for monitoring bone changes which occur in the early years following menopause (i.e., age range approximately 50-65 years).

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**Technological Characteristics:**

The MiniOmni employs a hand-held probe designed to measure SOS values. The probe is connected by a cable to the MiniOmni Main Unit. During measurement, the probe is applied directly to the skin.

High frequency acoustic waves, at a center frequency of 1.25MHz, are produced by two transducers in the probe. The ultrasound waves are conducted along the patient's bone and detected by two different transducers in the same probe. The SOS of the bone is measured by the device.

The device software compares the SOS result with the SOS of a young healthy population, as well as an age-matched population, using an embedded reference database, and reports the comparison in the form of a T-score and a Z-score.

The user interfaces with the MiniOmni by means of items that are not supplied with the device, including PC (or laptop computer), keyboard, optional foot-pedal and printer. The operator uses these items mainly to input patient information into the PC and also for entering other administrative input required in order to operate the system.

**Performance Data:**

The performance of the MiniOmni is identical to that of the predicate device.

**Comparison with predicate device:**

The predicate device is the Sunlight 7000S Omnisense Bone Sonometer, which was the subject of PMA P990035, approved 20 January 2000.

| Item | Omnisense 7000S (predicate) | MiniOmni (subject device) |
|---|---|---|

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| Item | Omnisense 7000S (predicate) | MiniOmni (subject device) |
|---|---|---|
| Indications for use | The Sunlight Omnisense 7000S Ultrasound Bone Sonometer is a non-invasive device that is designed for the quantitative measurement of the signal velocity of ultrasound waves ("Speed of Sound" or "SOS" in m/sec) propagating at multiple skeletal sites (i.e., the distal one-third of the radius, the proximal third phalanx and the fifth metatarsal). SOS provides an estimate of skeletal fragility.<br>The output is also expressed as a T-score and a Z-score, and can be used in conjunction with other clinical risk factors as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and, ultimately, in the determination of fracture risk.<br>Multiple skeletal site testing provided clinicians with alternatives if one site is not accessible and with additional skeletal information (i.e., from bones with different combinations of cortical and cancellous material and from weight bearing and non-weight bearing sites) that assists in diagnosing osteoporosis and risk fracture.<br>The SOS measured by MiniOmni has a precision error low enough in comparison with the expected annual change in a patient's measurement to make it suitable for monitoring bone changes which occur in the early years following menopause (i.e., age range approximately 50-65 years). | Same |
| Measurement Mode | Speed of Sound (SOS) | Same |
| Measurement Precision | 0.40%- 0.81% short term in- vivo precision (skeletal site dependent) 0.25%-0.50% instrumental accuracy (probe dependent) | Same |
| Measurement Time | Approximately 1 to 1½ minutes (3 to 5 measurement cycles of approximately 20 seconds each) | Same |
| Probe compatibility | Three proprietary multi-transducer probes; Centre frequency = 1.25 MHz. | Four proprietary multi-transducer probes; Centre frequency = 1.25 MHz. |
| Operating System | MS Windows 95 | MS Windows XP, Windows 7 |
| User Interface | Mouse and keyboard driven GUI (Windows 95) and foot pedal | Mouse, keyboard and foot pedal |
| Algorithms | As described in PMA 990035 | Same |
| Calibration | Calibration free; Daily System Quality Verification (SQV) with Phantom is required | Same |
| System portability | Bench mounted | Portable |
| Screen size | SVGA 14" Monitor (CRT) or flat-panel (LCD) | Any size (software installed on user's computer) |
| Printers | Standard PC printers (not supplied)<br>Supported Printers: HP DeskJet 690 Series, 710C and 815C; Epson 440; Lexmark 5700; and Cannon BJC 4400 Series. | Any printer compatible with MS Windows XP / Windows 7 and as specified in section 4.6.2 of the User Guide |

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| Item | Omnisense 7000S (predicate) | MiniOmni (subject device) |
|---|---|---|
| Power | 100-240 VAC (per specified order), 50Hz to 60 Hz | Same |
| Power consumption | Approximately 85 VA | Rated steady state input consumption: 3 W |
| Dimensions (w x h x d) | 390 mm x 130 mm x 330 mm + Video Display monitor | 140 mm x 223 mm x 140 mm |
| Weight | Approximately 7 kg | Approximately 1 kg |
| Electrical safety | Complies with IEC 60601-1:1988, including Amendments 1 and 2 | Complies with IEC 60601-1: 1988 including Amendments 1 and 2; IEC 60601-2-37: 2001 including Amendments 1 and 2; and IEC 60601-1: 2005 |
| Electromagnetic compatibility | Complies with IEC 60601-1-2:1993 | Complies with IEC 60601-1-2: 2007 |
| Power supply | Medical grade power supply | Same |
| Operating Environment | Temperature: +10°C to +35 °C<br>Humidity: 30% to 75%RH, non-condensing<br>Atmospheric Pressure: 700 to 1060 Pc | Same |
| Storage Environment | Temperature: +0 °C to 50°C<br>Humidity: 10% to 90% RH, non-condensing | Same |
| Backup Platform | Standard 3.5 inch drive (1.44 MB) Zip ™ drive (100 MB) | Local PC/ USB device/ network storage |
| Acoustic Module | Algorithm, analog card and probes | Same |

On the basis of the above comparison, the only differences between the MiniOmni device and the Omnisense 7000 device are in the following areas:

1) The PMA-approved Omnisense 7000S device consisted of: a desktop personal computer Main Unit; a video display monitor; a keyboard; a set of earphones; ultrasound probes; SQV phantom; foot pedal; one spring- loaded positioning gauge; and a cushion hand support.

   The MiniOmni has eliminated the personal computer Main Unit, the video display monitor, a keyboard and the earphones. The MiniOmni has a separate main unit with a single 'Measure' button on top connected to the user's computer / laptop, as specified by the User Guide.

2) The PMA-approved Omnisense 7000S device analog and digital functions are performed by two separate PCBs connected to the PC motherboard through a PCI. The MiniOmni uses a single PCB containing both the analog and digital components connected to the PC via USB.

3) The PMA-approved Omnisense 7000S device uses three slots for connection of the different probes. The MiniOmni has one slot suitable for all probe types.

The above differences between the MiniOmni and the Omnisense 7000S do not have any effect on the safety and efficacy of the device.

**Conclusion:**

Based on the information contained within this submission, it is concluded that the BeamMed Sunlight MiniOmni Bone Sonometer is substantially equivalent to the identified predicate device already in interstate commerce within the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 12 2011

Ms. Rita Koremblum
QA/RA Manager
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ISRAEL

Re: K110646
Trade/Device Name: Sunlight MiniOmni Ultrasound Bone Sonometer
Regulation Number: 21 CFR 892.1180
Regulation Name: Bone sonometer
Regulatory Class: II
Product Code: MUA
Dated: September 11, 2011
Received: September 13, 2011

Dear Mr. Koremblum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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# Indications for Use Statement

**510(k) Number (if known):** Not known

**Device Name:** Sunlight MiniOmni Ultrasound Bone Sonometer

**Indications for Use:** The Sunlight MiniOmni Ultrasound Bone Sonometer is a non-invasive device that is designed for the quantitative measurement of the signal velocity of ultrasound waves ("Speed of Sound" or "SOS" in m/sec) propagating at multiple skeletal sites (i.e., the distal one-third of the radius, the proximal third phalanx and the fifth metatarsal). SOS provides an estimate of skeletal fragility.

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| | | | | |
|---|---|---|---|---|
| Prescription Use<br>(Part 21 CFR 801 Subpart D) | ☒ | AND/OR | Over-The-Counter Use<br>(21 CFR 801 Subpart C) | ☒ |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110646